

9125 '99 EET-8 P3:37

September 29, 1999

10/5/94

The Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C. Street S.W. Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statement:

(1) Betaine Hydrochloride can really be considered an acidifying agent for the entire gastrointestinal system.*

This statement is made for a dietary supplement containing a proprietary blend of betaine hydrochloride, ammonium chloride, calcium lactate, pepsin (1:10,000), and magnesium citrate. Other ingredients include cellulose, lactose, and calcium stearate. And the name of the product is Betaine Hydrochloride.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden

Standard Process Inc.

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